FEB 0 5 2003

510(k) Summary
K022877

Vision Chips, Inc.
OBserver™ OB/GYN Ultrasound Reporting and Imaging System

Name of Submitter:

Vision Chips, Inc.
27111 Aliso Creek Road, Suite 120
Aliso Viejo, CA 92656
(949) 362-0565
(949) 362-0591 Fax

Contact Person:

Ronald "Jock" Philip, President

Date of Summary:

August 29, 2002/Revised 11/25/02

Device and Common Names:

Name of Device: OBserver OB/GYN Ultrasound Reporting, Information & Imaging System
Common Name: Image Acquisition, Review and Reporting System
Classification Name: Picture Archiving and Communications System

Device Description:

General Description

The Vision Chips ultrasound reporting and imaging system consists of comprehensive reporting and image archiving software for use in the field of obstetrics and gynecology. It enables physicians to generate reports documenting the results of ultrasound exams and to view the images that were captured during those exams. The system also enables physicians to perform research on all data that have been entered into the program.

Ultrasound machines may transfer ASCII text based information to the system by means of a serial interface. Ultrasound images are received either by means of a standard frame grabber connected to the ultrasound video output or directly across the network using DICOM protocols. Still images are stored as standard jpegs or in DICOM format, cine loops are stored as mpegs, AVIs or in multi frame DICOM format.

All hardware required for the system, including computers, storage devices, monitors and frame grabbers, consists of standard, off the shelf components.

Indications for Use

OBserver Ultrasound Reporting and Imaging System is intended to automate and enhance the process by which ultrasound examination information is entered and reported and by which ultrasound images are stored and reviewed by physicians in the field of maternal-fetal medicine. The system also provides significant research data for academic institutions.

User Characteristics

OBserver is a comprehensive Ob/Gyn Ultrasound and Antepartum surveillance(NST, CST, BPP & AFI) information reporting system. It allows perinatologists, obstetricians, gynecologists, radiologists and ultrasound technicians to capture examination data and images from ultrasound machines and to generate electronic and printed medical reports from them.

Substantial Equivalence:

OBserver Ultrasound Reporting and Imaging System is substantially equivalent to the following legally-marketed devices:

1) ALI Ultras PACS and comPACS (K963610)
2) R4's Remote Fetal Medicine Ultrasound System. (K000443)
3) Digisonics OB-View (K970402)

OBserver Ultrasound Reporting & Imaging System, like R4's Remote Fetal Medicine Ultrasound System, Digisonics' OB-View, and ALI's includes review and reporting capabilities, ob/gyn calculations, and digital imaging. Vision Chips' OBserver, like R4's Fetal Ultrasound Reporting and ALI's comPACS, performs ob/gyn reporting and includes calculations to convert fetal measurements to gestational ages. They all have the ability to review ultrasound images captured during the course of the examination. The ultrasound images are captured and converted to digital format with the use of a frame grabber. They are saved as JPEG files on standard computer storage media. The Vision Chips and ALI systems will also accept images and other data that have been transmitted across a network in DICOM format. All of the systems run on Microsoft operating systems although the text reporting section of Vision Chips' system will also run on Macintosh operating systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

Mr. Ronald Philip
President
Vision Chips, Inc.
27111 Aliso Creek Road #120
VIEJO CA 92656

Re: K022877
Trade/Device Name: Observer Ultrasound Reporting and Imaging System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: November 26, 2002
Received: November 26, 2002

Dear Mr. Philip:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K022877

Device Name: OBserver™ Ultrasound Reporting and Imaging System

Indications For Use:

OBserver Ultrasound Reporting and Imaging System is intended to automate and enhance the process by which ultrasound examination information is entered and reported and by which ultrasound images are stored and reviewed by physicians in the field of maternal-fetal medicine. The system also provides significant research data for academic institutions.

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022877

Prescription Use √

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)